510(k) SUMMARY

(in accordance with 21 CFR 807.87(b) and 21 CFR 807.92)

Loutrex Topical Cream

SEP 6 2012

1. Submitter's Name, Address, Telephone Number, Contact Person and Date Prepared

RRI Group
248 Latitude Lane, Suite 104
Lake Wylie, SC 29710

Phone: (803) 831-7657
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Contact Person: Lara Noah, Sr. Manager Regulatory Affairs
lnoah@rrriint.com

Date Prepared: February 17, 2012

2. Name of Device and Name/Address of Sponsor

Loutrex Topical Cream

Acella Pharmaceuticals, LLC
9005 Westside Parkway
Alpharetta, GA 3009

Common or Usual Name

Hydrogel wound dressing

Classification Name

Device	Unclassified
Review Panel	General & Plastic Surgery
Product Code	FRO
Unclassified Reason	Pre-Amendment
Submission Type	510(k)

3. Substantial Equivalent Devices:

Acella Pharmaceuricals, LLC believes that Loutrex Topical Cream is substantially equivalent to the currently marketed devices, Sinclair Skin Emulsion (a.k.a Sincalir Seborrhea Emulsion), cleared under K050158 and also cleared under K111168, distributed by Promius Pharma, LLC as Promiseb® Topical Cream.

4. Device Description:

Loutrex Topical Cream is a non-sterile, white to off-white water based emulsion intended for topical application applied 3 times per day or as needed. It is presented as a Prescription (requires a physician diagnosis of disease state) for use.

5. Intended Use Indications for Use:

Loutrex Topical Cream

Rx Use: Loutrex Topical Cream is indicated to manage and relieve the signs and symptoms of seborrhea and seborrheic dermatitis such as itching, erythema, scaling, and pain. Loutrex Topical Cream helps relieve dry, waxy skin by maintaining a moist wound and skin environment, which is beneficial to the healing process.

6. Summary of the Technological Characteristics of the Device Compared to the Predicate Device(s):

All products referenced are non-sterile emulsions that are applied topically to relieve the symptoms of various dermatoses.

7. Conclusions:

Functional and performance testing has been conducted to assess the safety and efficacy of Loutrex Topical Cream and the results are satisfactory.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Acella Pharmaceuticals, LLC
% RRI Group
Ms. Lara Noah
Senior Manager, Regulatory Affairs
248 Latitude Lane, Suite 104
Lake Wylie, South Carolina 29710

SEP 6 2012

Re: K120730
Trade/Device Name: Loutrex Topical Cream
Regulatory Class: Unclassified
Product Code: FRO
Dated: August 30, 2012
Received: August 30, 2012

Dear Ms. Noah:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

FOR

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indication for Use

510(k) Number (if known): K120730

Device Name: Loutrex Topical Cream

Indications for Use:

Under the supervision of a healthcare professional, Loutrex Topical Cream is indicated to manage and relieve the signs and symptoms of seborrhea and seborrheic dermatitis such as itching, erythema, scaling, and pain. Loutrex Topical Cream helps relieve dry, waxy skin by maintaining a moist wound and skin environment, which is beneficial to the healing process.

Prescription Use: X AND/OR Over-the-Counter Use: ____

(21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K120730